



22 August 2008

Guidelines

Electronic applications - National Procedures, DCP, MRP -

Introduction

Reference is made to Notice to Applicants, Volume 2A, Chapter 7, and Volume 6A, Chapter 7, concerning certain information about the dossier, i.e. electronic version and paper copy, for human and veterinary products respectively.

This document contains information supplementary to Notice to Applicants.

Human medicinal products

An electronic version of the application is preferable. Please note that notwithstanding Notice to Applicants, neither Module 1 nor Module 2 has to be submitted in paper form.

Applications should be in eCTD or NeeS format, submitted on CD-Rom or DVD.

eCTD

Reference is made to the EMEA website at <http://esubmission.emea.europa.eu/>.

NeeS

The electronic version of the dossier shall be in accordance with [Guidance for Industry on Providing Regulatory Information in Electronic Format: Non-eCTD electronic Submissions \(NeeS\)](#)

Veterinary medicinal products

An electronic version of the application is preferable. Please note that notwithstanding Notice to Applicants, no documents have to be submitted in paper form.

The electronic version of the dossier shall be in accordance with [Guideline for the specifications of e-submission of veterinary medicinal products documents](#). Cf. also [Questions and Answers](#).

Iceland as Reference Member State (RMS)

When Iceland is acting as RMS in Decentralised Procedures (DCP) or Mutual Recognition Procedures (MRP), applicants are advised to contact the Icelandic Medicines Control Agency concerning specific requirements for the dossier.